



Advance the potential of your cell culture

Discover in-process control solutions

# Knowledge is the power – complete solutions for reliable in-process control

Discover more, so you can do more

Maintaining optimal cell culture conditions throughout the cell culture and fermentation process is vital to producing high yields of top-quality biopharmaceuticals. Accurate monitoring of complete culture physiology inside bioreactors is simple and fast with Cedex Analyzers. This family of instruments performs precise measurements and can detect subtle changes in nutrients, metabolites, or cell morphology and growth, enabling informed decisions and fast time response.

Featuring a broad and continuously growing test portfolio, the Cedex Analyzer Family combines the functionalities of multiple instruments to deliver powerful testing capabilities with reduced workflow complexity. These robust platforms were designed for diagnostic applications and then adapted to withstand continuous operation in pharmaceutical process development and industrial production. Furthermore, they have been rigorously tested in our own manufacturing. Cedex Analyzers support the Quality by Design (QbD) approach and complete process automation, allowing high level of success for cell culture and fermentation both in development and in GMP manufacturing environments.



## **Cedex Analyzer family provides:**

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- Detailed understanding of the bioprocess and influencing factors
- Comprehensive testing capabilities that increase productivity and quality
- Peace of mind that the instruments function reliably
- Process safety instead of security and compliance with the strict regulatory requirements



# Reliable in-process control for all stages of bioprocess development and production

Instruments	Test capabilities	Sample capacity	Technology
<b>Cedex Bio Analyzer</b>	26 different assays for mammalian and microbial cultures, including IgG and LDH, continuously expanding menu	8	Photometric analyzer, Ion selective electrodes
<b>Cedex Bio HT Analyzer</b>		96 + 30	
<b>Cedex HiRes Analyzer</b>	Cell density, viability, aggregation rate, and morphological parameters, such as cell diameter and cell compactness	20	High resolution scanner imaging, Trypan blue exclusion method

## Benefits in your process

### Early process research

- Develop a full understanding of the fermentation process and all critical influences

### Bioprocess development

- Develop tight control of bioprocess
- Generate accurate process models
- Meet Quality by Design (QbD) and Design of Experiment (DoE) requirements
- Obtain comparable data from both the Cedex Bio and Bio HT. Easily transfer technology to a manufacturing environment anytime and at any stage

### Bioprocess manufacturing

- Maintain reliable control of your bioprocess



Cedex HiRes Analyzer



Cedex Bio Analyzer



Cedex Bio HT Analyzer

# Take control of your bioprocess – Cedex Analyzer Family

## Gain tight control

With **high precision and data integrity**, Cedex Analyzers are the basis for a reliable bioprocess control, perfectly supporting your **Quality by Design** approach.

- Reliable time-course profiles can be translated into **predictive models of the bioprocess** to detect and to resolve problems as early as possible by implementing real-time measures.
- Accurate and reliable analytics allow full characterization of influencing factors.
- Well-informed decisions can be made to safeguard **optimal culture conditions**, resulting in consistently **high product quality** and yield.

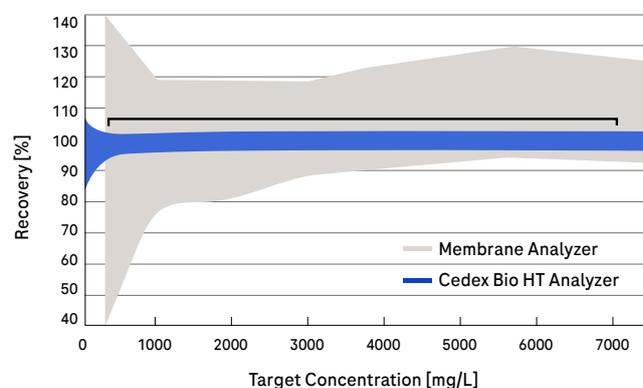


01  
**Accuracy in cell analysis with high-resolution imaging:** Cedex HiRes Analyzer image of a living cell.

## Boost productivity

Along with proven technology and ease of use, the Cedex Analyzers allow for bioprocess **workflow optimization** from start to finish.

- **Data reproducibility and consistency** is obtained, independent of the instrument, the process stage, site or department.
- **One analyzer family** to measure key nutrients, metabolite concentrations, as well as cell density, viability and morphology.
- Cedex Bio and Bio HT Analyzers run a **highly versatile menu of tests** in mammalian cell, bacterial, or yeast cultures.
- **Streamlined sample management** with easy-to-use, barcoded reagents and consumables and front-loading, tailored to each analyzer.



02

**Precision in metabolite testing - comparison with membrane technology in glucose analysis:** Recovery of glucose concentration was determined in parallel using the Cedex Bio HT Analyzer and a membrane analyzer (Roche evaluation data).

## Count on quality technology

The Cedex Analyzer family uses industry-proven diagnostics technology and is developed to meet GMP requirements (Good Manufacturing Practice). These platforms are designed to **support process development and industrial production at Roche Pharmaceuticals.**

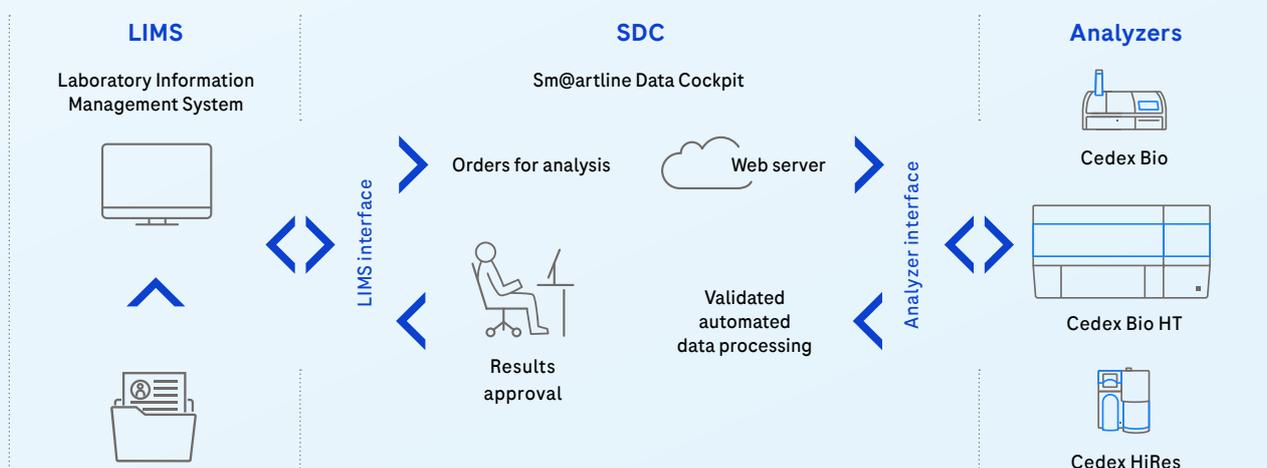
Cedex Analyzers:

- are **robust** instruments tolerating **continuous operation** and rigorous use.
- require minimal user handling, **preventing manual errors** and providing **process safety**.
- use **automated and convenient maintenance** procedures.
- **minimize costs and complexity** since no backup instrument is needed.

## Improve workflow efficiency

**Online integration** of the analyzers used in biomanufacturing is a mandatory requirement in today's state-of-the-art bioprocessing. The Cedex Analyzers can be readily integrated into closed loop systems for **automated in-process control, providing:**

- **validated integration** with the Sm@artline Data Cockpit middleware enables the virtual consolidation of samplers, analyzers, and sensors.
- **around-the-clock monitoring** of cell culture conditions with immediate response.
- secure result transfer to **LIMS or MES** systems.
- **complete traceability** and compliance tailored to each analyzer.



**Regulatory Disclaimer**

For use in quality control/manufacturing process only.

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